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| 21839 | 7590 07/28/2004 | | EXAMINER | | |
| BURNS DO | ANE SWECKER & MAT | CHEU, CHANGHWA J | | | |
| POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404 | | | ART UNIT | PAPER NUMBER | |
| | , | | 1641 | | |
| | | | DATE MAILED: 07/28/2004 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Application No. Applicant(s) | | | | |
|--|---|---|---|----------------------------|--|--|--|
| | | 10/076,838 | MAJUMDAR ET A | MAJUMDAR ET AL. | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | Jacob Cheu | 1641 | | | | |
| Period fo | The MAILING DATE of this communication Reply | on appears on the cover sheet w | vith the correspondence ad | dress | | | |
| THE - External control | ORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNICAT nsions of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communicate period for reply specified above is less than thirty (30) day of period for reply is specified above, the maximum statutor reto reply within the set or extended period for reply will, by reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b). | FION. CFR 1.136(a). In no event, however, may a titon. Is, a reply within the statutory minimum of the period will apply and will expire SIX (6) MC by statute, cause the application to become A | reply be timely filed irty (30) days will be considered timely INTHS from the mailing date of this co | <i>y.</i> ommunication. | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed or | n <u>12 May 2004</u> . | | | | | |
| 2a)⊠ | This action is FINAL . 2b) | This action is non-final. | | | | | |
| 3)[| | | | | | | |
| Disposit | on of Claims | | | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) <u>1,3-7,12-14,16-18 and 22-35</u> is 4a) Of the above claim(s) is/are w Claim(s) is/are allowed. Claim(s) <u>1,3-7,12-14,16-18 and 22-35</u> is Claim(s) is/are objected to. Claim(s) are subject to restriction | ithdrawn from consideration. /are rejected. | | | | | |
| Applicati | on Papers | | | | | | |
| 9)[| The specification is objected to by the Ex | aminer. | | | | | |
| 10) | 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| | Applicant may not request that any objection | | • | | | | |
| 11) | Replacement drawing sheet(s) including the The oath or declaration is objected to by | | | | | | |
| Priority ι | inder 35 U.S.C. § 119 | | | | | | |
| 12) a)[| Acknowledgment is made of a claim for for All b) Some * c) None of: 1. Certified copies of the priority docu 2. Certified copies of the priority docu 3. Copies of the certified copies of the application from the International E | uments have been received. uments have been received in A e priority documents have beer Bureau (PCT Rule 17.2(a)). | Application No n received in this National S | Stage | | | |
| Attachment | (e) | | | | | | |
| / | e of References Cited (PTO-892) | 4) Intention | Summary (PTO-413) | | | | |
| 2) ☐ Notice 3) ⊠ Inform | e of Draftsperson's Patent Drawing Review (PTO-9-nation Disclosure Statement(s) (PTO-1449 or PTO/-10(s)/Mail Date | 18) Paper No(| s)/Mail Date Informal Patent Application (PTO- | -152) | | | |
| | | | | | | | |

DETAILED ACTION

Applicant's amendment filed on 5/12/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

- 1. Claims 2, 8-11, 15, 19-21 are cancelled.
- 2. Claims 23-35 are added to the instant application.
- 3. Currently, claims 1, 3-7, 12-14, 16-18, 22-35 are under examination.

Claim Objections

Claims 3, 5, 6, 7, 16-18 are objected because those claims improperly depend on cancelled claims 2 and 15. Corrections are needed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description/New Matter

2. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 29, applicant adds this new claim reciting "a control environment." However, there is no support from the specification indicating or defining "a control environment."

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 1, 3-7,12-13, 22-24; 14, 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 5, "each cantilever array block being configured to be responsive to a chemical-mechanical force created by presence of a predetermined substance upon exposing the cantilevers in the cantilever array block to the substance" is vague and indefinite. It is not clear whether any material needed for the recited cantilever other than the "predetermined substance" for the detection of the light diffraction because in claim 4 applicant specifies that the force is created by antigen-antibody interaction. It is also not clear where this material other than the predetermined substance, if exists, is located on the cantilever. Similarly, claims 14, 30, 32 and 33 share the same problem.

With respect to claim 1, last line, "wherein the apparatus does not require external power" is vague and indefinite. It is not clear what is this "external *power*." (emphasis added) Does applicant mean no external power at all, such as electricity? Similarly, claims 32 and 33 share the same problem.

With respect to claim 1, last line, "wherein the apparatus does not require external power" is vague and indefinite. It is not clear how this limitation relates to the diffraction pattern of light in response to the presence of the substance.

With respect to claim 1, "line 7, "a predetermined substance" is vague and indefinite. It is not clear what is this "predetermined substance." Similarly, claims 3, 5-7, 22-23, 14, 16-18, 30-31, 33-35 share the same problem. Applicant needs to define the "predetermined substance."

With respect to claim 26, line 10, "the physical property" lacks antecedent basis.

With respect to claim 26, line 10, "the physical property" is vague and indefinite. It is note clear what "the physical property" applicant refers to.

With respect to claim 29, line 3, "a control environment" is vague and indefinite. It is not clear what is "a control environment."

With respect to claim 30, line 8, "the physical property' lacks antecedent basis.

With respect to claim 30, line 8, "the physical property" is vague and indefinite. It is not clear what physical property applicant refers to. Similarly, claim 33 shares the same problem.

With respect to claim 33, line 7, "interleaved" is vague and indefinite. It is not clear what applicant means "interleaved" in the claim language.

With respect to claim 35, line 3, "force-creating material" is vague and indefinite. It is not clear what is this "force-creating material."

With respect to claim 35, "incident light" is vague and indefinite. It is not clear what applicant means "incident light."

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. Claims 1, 3, 5-7, 12-14, 16-18, 22-23, 25-27, 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al (US 5908981) in view of Quate et al. (6436647).

Atalar et al. teach a light deflection sensor for a microcantilever includes an array of cantilever blocks, where the block contains a plurality of cantilever fingers, and the cantilever fingers form optical change grating and can be used to measure the deflection pattern providing the indicia of the micro-force due to the presence of a predetermined substance. (See abstract, Figure 6, Figure 12, Interdigital Cantilever) Atalar et al. also disclose that Atomic Force Microscopy (AFM) used in detection the diffraction of the cantilever can be operated in different modes, such as contact mode, in which the tip rides over the surface, or in the non-contact mode or attractive mode, in which the

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resonant frequency of a vibrating cantilever positioned very near the surface (See Background, Col. 1, line 15-20). The contact mode does not require external forces, such as resonant frequency used in the non-contact or attractive mode (Col. 3, line 10-34).

However, Atalar et al. do not specifically teach using chemical-mechanical micro-force created by the presence of a predetermined substance to detect presence of the substance. Quate et al. teach immobilizing different binding partners, such as DNA probe biomolecules, on a plurality of cantilever array block to create chemical-mechanical force in response to different predetermined substances in the sample (Col. 4, line 30-40; Col. 6, line 18-30). The block of plurality of cantilever array is configured to be responsive to the predetermined substance(s), e.g. cantilever fingers bend when binding occur between the probe on the cantilever and the target molecules (Figure 2-4). The binding of the binding pairs, such as DNA-DNA hybridization, on the cantilever can cause optical light deflection reflected in control and test sample environments (claims 1 and 10, 18; Col. 6, line 35-60). The method taught by Quate et al. can be performed by the Atomic Force Microscopy which inherently includes different modes as discussed before (Col. 2, line 32-40). The advantages offered by Quate et al. reference is that it provides accuracy for binding specificity, and economically low-cost for measuring multiple analytes (Col. 6, line 55-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Atalar et al. with the chemicalmechanical binding partners as taught by Quate et al. to detect biological samples with efficiency and low-cost.

8. Claims 4, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. in view of Thundat et al. (US 6289717).

Atalar et al. reference has been discussed but does not explicitly teach using antigenantibody as the chemical-mechanical force to detect the presence of the predetermined substance in the sample. Thundat et al. teach using the chemical-mechanical force as a

detection means to measure a low level of predetermined substance in a sample (Col. 2, line 28-31). Thundat et al. teach immobilizing antigen or antibody on the cantilever and to determine the light deflection from the cantilever surface before, during and after bending of the cantilevers due to the binding of the antigen-antibody (Col. line 60-68 to Col. 7, line 1-9). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to provided Atalar et al. with the antigen-antibody type of binding immobilized on the cantilever as taught by Thundat et al. because the benefits providing specificity in measuring low level of target molecules in a test sample.

Response to Applicant's Arguments

9. Applicant's arguments with respect to claims 1, 3-7, 12-14, 16-18 have been considered but are most in view of the new ground(s) of rejection.

"External Power"

Applicant amends the instant claims and adds a feature "no external power is required" for the recited apparatus and method. Applicant pointed out that the instant cantilevers "are not oscillated, as commonly done with prior art cantilevers used in sensing application" whereas the Atalar et al. reference cantilevers "are driven by electrostatic forces to oscillate at their resonant frequency" (See Specification page 8, line 7-10; Remarks, page 13, last paragraph). However, examiner had pointed out in this Office Action that Atalar et al. reference teach using AFM in different modes, e.g. contact, noncontact or attractive modes. Examiner considers that Atalar et al. reference can apply to all different modes of AFM for operation, including no external force contact mode, because AFM is merely a detection tool to measure the force created by bending the cantilever in response to the binding of the target substance to the cantilever.

Furthermore, examiner also points out in this Office Action that it is not clear what is the relationship between this "no requirement of external power" to the measurement of the

target molecules (See Rejections under 35 USC 112, second paragraph). Active steps are required to indicate how to measure the change in the cantilever in response to the presence of target molecules with respect to this feature. Additionally, it is also not clear whether this "external power" includes general electricity needed for assay (for example, plug power into this apparatus). If indeed the current invention does not require any electrical power, how can applicant still use laser source and a photodiode in conjunction with the instant invention?

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

CHINCO

Examiner

Art Unit 1641

John ME

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07/26/04

July 19, 2004